# **COVID-19 Update**

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10/21/21





### ACIP Findings-Additional vs Booster Dose

- Additional vs Booster Dose
  - Additional dose after an initial primary vaccine series: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
  - Booster dose: a dose of vaccine when the initial sufficient immune response to a primary vaccine series is likely to have waned over time.
    - Only Pfizer is eligible for booster
    - Certain populations
    - Dosing is 6 months after initial series
- For more information, visit:
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html
  - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

## Frequently Asked Questions for 3rd Dose of mRNA Vaccines



#### Should everyone receive 3rd dose?

 No, this currently only applies to those individuals who have been identified to meet certain immunocompromised conditions and those who have received a mRNA vaccine.



#### What if I received the 1 dose Janssen (Johnson and Johnson) vaccine?

 Individuals who received the Janssen (Johnson and Johnson) vaccine should NOT receive an additional dose of ANY COVID-19 vaccine at this time.



#### What conditions qualify someone for a third dose?

• In order to determine eligibility for the vaccine, please discuss your health condition with your healthcare provider or pharmacist.

#### Immunocompromised conditions include:

- Active treatment for solid tumor and hematologic malignancies.
- Receipt of solid-organ transplant and taking immunosuppressive therapy.
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes).
- · Advanced or untreated HIV infection.
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.



#### Should antibody testing be used to determine if a 3rd dose is needed?

- No. Antibody testing is not recommended for vaccine decision-making or to assess immunity following vaccination.
- 5

#### When will additional doses be available for the general public?

 At this time, booster doses are not recommended for the general public. The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) will be reviewing vaccine effectiveness data to determine if booster doses will be recommended in the coming months.



#### Where can I find additional information?

COVID-19 Vaccines for Moderately to Severely Immunocompromised People FDA EUA announcement

ACIP Presentation Slides: August 13, 2021 Meeting

ACIP's General Guidance on Vaccination of the Immunocompromised

3rd doses for IMMUNOCOMPROMIZED are needed NOW

Schedule an appointment to get vaccinated if it is has been at least 28 days since your 2nd dose today.



### Pfizer Booster Doses are Here

September 23<sup>rd</sup>, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommended certain populations receive a **booster shot of Pfizer-BioNTech's COVID-19 Vaccine at least six months after the completion of their Pfizer vaccine primary series.** 

The recommendations are as follows:

- people 65 years and older **should** receive a booster shot
- residents in long-term care settings **should** receive a booster shot
- people aged 50 to 64 with <u>certain underlying medical conditions</u> should receive a booster shot;
- people 18 to 49 who are at high risk for severe COVID-19 due to <u>certain</u> underlying medical conditions may receive a booster shot
- people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot

### Who is eligible for Pfizer-BioNTech's COVID-19 Vaccine Booster?

1

#### 65 years and older

People 65 years and older should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.

2

#### 50 to 64

People aged 50 to 64 with certain underlying medical conditions should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.

3

#### **LTC** Residents

Residents in long term care settings should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.

4

#### 18 to 49

People 18 to 49 who are at high risk for severe COVID-19 due to certain underlying medical conditions may, receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

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#### 18 to 64

People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.





- Q: When can I get a COVID-19 vaccine booster if I am NOT in one of the recommended groups?
- A: Additional populations may be recommended to receive a booster shot as more data becomes available. The COVID-19 vaccines approved and authorized in the United States continue to be effective at reducing risk of severe disease, hospitalization, and death. However, the virus that causes COVID-19 constantly evolves. Experts are looking at all available data to understand how well the vaccines are working for different populations. This includes looking at how new variants, like Delta, affect vaccine effectiveness

- Q: If we need a booster shot, does that mean that the vaccines aren't working?
- A: No. COVID-19 vaccines are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.
- Q: What should people who received Moderna or Johnson & Johnson's Janssen vaccine do?
- A: The Advisory Committee on Immunization Practices (ACIP) and CDC's recommendations are bound by what the U.S. Food and Drug Administration's (FDA) authorization allows. At this time, the Pfizer-BioNTech booster authorization only applies to people whose primary series was Pfizer-BioNTech vaccine. People in the recommended groups who got the Moderna or J&J/Janssen vaccine will likely need a booster shot. More data on the effectiveness and safety of Moderna and J&J/Janssen booster shots are expected in the coming weeks. With those data in hand, CDC will keep the public informed with a timely plan for Moderna and J&J

- Q: What are the risks to getting a booster?
- A: For many who have completed their primary series with Pfizer-BioNTech vaccine, the benefits of getting a booster shot outweigh the known and potential risks. So far, reactions reported after the third Pfizer-BioNTech shot were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, serious side effects are rare, but may occur.
- Q: Does this change the definition of "fully vaccinated" for those eligible for booster shots?
- A: People are still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine. This definition applies to all people, including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster shot.

- Q: Can you explain these "permissive" recommendations related to people 18 to 49 with underlying medical conditions, and people 18 to 64 who may be exposed due to occupational/institutional setting? How are these different from the other two recommendations?
- A: Adults 18–49 who have underlying medical conditions are at increased risk for severe illness from COVID-19, as are people 18-64 are in an occupational or institutional setting where the burden of COVID-19 infection and risk of transmission are high. However, that risk is likely not as high as it would be for adults 50 years and older who have underlying medical conditions, or people who live in long-term care settings. With the lower risk, the data do not support that everyone who falls into this group should get a booster shot. Therefore, CDC's recommendation is not as strong for these populations, but still allows a booster shot to be available for those who would like to get one. People 18 and older who are at high risk for severe COVID-19 due to underlying medical conditions or their occupation should consider their individual risks and benefits when making the decision of whether to get a booster shot. This recommendation may change in the future as more data become available.
- Q: Will providers accept anyone who says they're eligible to receive a booster shot? Will people need to show a doctor's note/prescription or other documentation?
- A: It's important to note that individuals can self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered. This will help ensure there are not additional barriers to access for these select populations receiving their booster shot.

Third
Additional
Dose and
Booster Dose
Attestation
Forms

		PEF label	
3 <sup>rd</sup> Additional Dose and	DOCUMENT#: _		
Booster Dose COVID-19 VACCINE	HID/LOC/SITE: _		
ADMINISTRATION RECORD			-
NAME: ID/SO	CIAL SECURITY#	ŧ	
ADDRESS:			

NAME: ID/SOCIAL SECURITY#:
ADDRESS:
STREET CITY COUNTY STATE ZIP BIRTHDATE; PHONE NUMBER:
RACE: (Check ONE or MORE)   (W) White   (B) Black or African American   (N) American Indian or Alaska Native*   (A) Asian   (H) Native Hawaiian or Other Pacific Islander   ETHNICITY: Hispanic or Latino   Yes or   No SEX: (Check ONE)   Male   Female   How many in HOUSEHOLD:   Annual INCOME: \$   Income NOI Given
DO YOU HAVE MEDICAID? TYES* TO IF YES, MEDICAID NUMBER:
DO YOU HAVE <b>MEDICARE</b> ? □YES □NO IF YES, <b>MEDICARE NUMBER</b> :
DO YOU HAVE <b>HEALTH INSURANCE</b> ? □YES □NO+ IF YES, COMPANY NAME:
YOU or YOUR CHILD ARE LESS THAN 19yrs old AND HAVE HEALTH INSURANCE COVERAGE:
☐ YES, the insurance does cover vaccines; ☐ NO, the insurance does not cover vaccines * *VFC sligible
The provider may keep this record in a medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the vaccine injection site, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.
I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of COVID-19 vaccine and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.
Received an organ transplant and am taking medicine to suppress my immune system; Received a stem cell ransplant within the last 2 years or an taking medicine to suppress the immune system; Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, WishottAldrich syndrome); Advanced or untracted HIV infection; Active treatment with high-dose corticosteroids or other drugs that suppress my immune response. Active treatment with high-dose corticosteroids or other drugs that suppress my immune response.  65 years or older  65 years or older  Residents in long term care setting  18-64 years old with underlying medical condition described by the CDC guidance  18 years or older with increased exposure due to occupational or institutional exposure  Having met the criteria, I am requesting the 3 <sup>rd</sup> dose of (circle one) Pfizer or Moderna or the booster dose of Pfizer and it has been
at least tince my last does of the (circle one) Pffare or Moderna vaccine.  I request that payment of authorized medical insurance benefit be made to  out my behalf or behalf of my child, for services received. I also authorize the provider to release medical information to Medicare, other third payors (insurance arriers, Medicaid, etc.) and their agents to determine payment for services. I am aware that should Medicare refuse payment for this service, I will be responsible for the cost. If I am covered by a billable private insurance, I am aware that I may be responsible for some additional charges not covered by my plan.
Vaccine Manufacturer: Vaccine Lot Number: Injection Site: Signature and Title of Provider: Provider#:
NOTES: ICD Code: Z23. Encounter for immunization
J. COVID-19-VACCINE:         J. ADMINISTRATION:           91300-Pfizer Vaccine         0003A – 3rd Dose of Pfizer
91301-Moderna Vaccine 0013A – 3rd Dose of Moderna
80000 Unspecified Procedure

LHD name		peril i	
LHD address		PEF label	
	DOCUMENT#:		
3rd Additional Dose and	l		
	HID/LOC/SITE: _		
Booster Dose COVID-19 VACCINE			

NAME:		RITY#:	
ADDRESS:			
	PHONE NUMBER:	STATE	ZIP
RACE: (Check ONE or MORE) (W) W	Other Pacific Islander ETHNICIT	(; Hispanic or Latino □Yes	or 🗆 No
SEX: (Check ONE)  Male  Female Ho	•		
DO YOU HAVE <b>MEDICARD</b> ? □YES* □ DO YOU HAVE <b>MEDICARE</b> ? □YES □	_		
DO YOU HAVE HEALTH INSURANCE? Policy#Subsc			
Policy# Subsc	riber Name	Group#	
YOU or YOUR CHILD ARE LESS THAN	19yrs old AND HAVE HEALTH INSUF	ANCE COVERAGE:	
VES, the insurance does cover vaccines:			
The provider may keep this record in a medical file that made the vaccine, the vaccine's special lot num address where the vaccine was given.			
I have had a chance to ask questions that were a and ask that the vaccine be given to me or to the	nswered to my satisfaction. I believe I unders person named above for whom I am authori	tand the benefits and risks of Co ted to make this request.	OVID-19 vaccine
<ul> <li>Received a stem cell transplant within</li> <li>Moderate or severe primary immunod</li> <li>Advanced or untreated HIV infection;</li> </ul>	umors or cancers of the blood; aking medicine to suppress my immune syste the last 2 years or am taking medicine to sup- efficiency (such as DiGeorge syndrome, Wilsko scheroids or other drugs that suppress my im- following criteria as defined by the CDG	m; press the immune system; ttAldrich syndrome); nune response. C and ACIP	below
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<ul> <li>Residents in long term care setting</li> <li>18-64 years old with underlying me</li> </ul>	posure due to occupational or institution		been days
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Patient Signature X

Provider Form

LHD Form

0013A – 3rd Dose of Moderna

# COVID-19 and Pregnancy

- The Centers for Disease Control and Prevention (CDC) recommends urgent action to increase Coronavirus Disease 2019 (COVID-19) vaccination among people who are:
  - pregnant,
  - recently pregnant (including those who are lactating),
  - who are trying to become pregnant now, or
  - who might become pregnant in the future



# COVID-19 and Pregnancy

- As of September 27, 2021
  - more than 125,000 laboratory-confirmed COVID-19 cases have been reported in pregnant people,
  - more than 22,000 hospitalized cases
  - 161 deaths.



# COVID-19 and Pregnancy

- Pregnant and recently pregnant people with COVID-19 are at increased risk for severe illness when compared with non-pregnant people.
- Severe illness includes illness that requires
  - hospitalization,
  - intensive care unit (ICU) admission,
  - mechanical ventilation
  - extracorporeal membrane oxygenation (ECMO)
  - death.

# COVID-19 AND Pregnancy

- Symptomatic pregnant people have
  - two-fold increased risk of requiring ICU admission, invasive ventilation, and ECMO
  - 70% increased risk of death.
- Pregnant people with COVID-19 are also at increased risk for
  - preterm birth
  - preeclampsia
  - coagulopathy
  - stillbirth



# COVID-19 AND Pregnancy

- Neonates born to people with COVID-19 are also at increased risk for admission to the neonatal ICU.
- Pregnant patients with COVID-19 can transmit infection to their neonates



### **Action Items**

- Review patients' COVID-19 vaccination status at each pre- and post-natal visit and discuss COVID-19 vaccination with those who are unvaccinated.
- Reach out to your patients with messages encouraging and recommending the critical need for vaccination.
- Remind patients that vaccination is recommended even for those with prior COVID-19 infections. Studies have shown that vaccination provides increased protection in people who have recovered from COVID-19.
- Support efforts to ensure people receiving the first dose of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna) return for their second dose to complete the series as close as possible to the recommended interval. Consider a booster dose in eligible pregnant persons.
- Communicate accurate information about COVID-19 vaccines and confront misinformation with evidence-based messaging from credible sources. For example, there is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men.